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INFORMATION DISCLOSURE  
STATEMENT  
Patent Application  
Docket No. ARYX-102XC4Z  
Serial No. 10/697,683

January 19, 2004

David Saliwanchik

David R. Saliwanchik, Patent Attorney



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit :  
Applicant(s) : Pascal Druzgala, Peter G. Milner  
Serial No. : 10/697,683  
Conf. No. :  
Filed : October 29, 2003  
For : Novel Enantiomeric Compounds for Treatment of Cardiac Arrhythmias  
And Methods of Use

Commissioner for Patents  
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§ 1.97 AND 1.98

Sir:

In accordance with 37 C.F.R. §1.56, the reference listed on the attached form PTO-1449 is being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. A copy of the cited document is enclosed.

The applicants respectfully assert that the substantive provisions of 37 C.F.R. §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,

David Saliwanchik

David R. Saliwanchik

Patent Attorney

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Attachments: Form PTO-1449 and copies of references listed therein



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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| <b>Substitute for form 1449A/PTO</b><br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |   |    | <b>Complete if Known</b> |                        |              |
|   |   |    | Application Number       | 10/697,683             |              |
|   |   |    | Filing Date              | October 29, 2003       |              |
|   |   |    | First Named Inventor     | Pascal Druzgala        |              |
|   |   |    | Art Unit                 |                        |              |
|   |   |    | Examiner Name            |                        |              |
| Sheet   | 1 | of | 2                        | Attorney Docket Number | ARYX-102XC4Z |

| U.S. PATENT DOCUMENTS |                       |  |                                |  |   |
|-----------------------|-----------------------|--|--------------------------------|--|---|
| Examiner Initials*    | Cite No. <sup>1</sup> | Document Number                            | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant<br>of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|                       |                       | Number - Kind Code <sup>2</sup> (if known) |                                |  |   |
|                       | U1                    | US-4,931,464                               | 06-05-1990                     | Grover <i>et al.</i>                               |   |
|                       | U2                    | US-4,962,095                               | 10-09-1990                     | Grover <i>et al.</i>                               |   |
|                       | U3                    | US-5,175,187                               | 12-29-1992                     | Baligadoo  |   |
|                       | U4                    | US-5,364,880                               | 11-15-1994                     | Druzgala   |   |
|                       | U5                    | US-5,440,054                               | 08-08-1995                     | Druzgala   |   |
|                       | U6                    | US-5,849,788                               | 12-15-1998                     | Druzgala   |   |
|                       | U7                    | US-6,362,223 B1                            | 03-26-2002                     | Druzgala <i>et al.</i>                             |   |
|                       | U8                    | US-6,372,783                               | 04-16-2002                     | Druzgala <i>et al.</i>                             |   |
|                       | U9                    | US-  |                                |  |   |
|                       | U10                   | US-  |                                |  |   |
|                       | U11                   | US-  |                                |  |   |
|                       | U12                   | US-  |                                |  |   |
|                       | U13                   | US-  |                                |  |   |
|                       | U14                   | US-  |                                |  |   |
|                       | U15                   | US-  |                                |  |   |
|                       | U16                   | US-  |                                |  |   |
|                       | U17                   | US-  |                                |  |   |
|                       | U18                   | US-  |                                |  |   |
|                       | U19                   | US-  |                                |  |   |
|                       | U20                   | US-  |                                |  |   |

| FOREIGN PATENT DOCUMENTS |                       |   |                                |  |   |                |
|--------------------------|-----------------------|---|--------------------------------|--|---|----------------|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T <sup>6</sup> |
|                          |                       | Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known) |                                |  |   |                |
|                          | F1                    | WO 94/29289 A   | 12-22-1994                     | Advanced Therapies, Inc.                           |   |                |
|                          | F2                    |   |                                |  |   |                |
|                          | F3                    |   |                                |  |   |                |
|                          | F4                    |   |                                |  |   |                |
|                          | F5                    |   |                                |  |   |                |
|                          | F6                    |   |                                |  |   |                |
|                          | F7                    |   |                                |  |   |                |
|                          | F8                    |   |                                |  |   |                |
|                          | F9                    |   |                                |  |   |                |
|                          | F10                   |   |                                |  |   |                |

|                    |                 |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08B (10-01)

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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

2

of

2

**Complete if Known**

|                        |                 |
|------------------------|-----------------|
| Application Number     | 10/697,683      |
| Filing Date            | April 15, 2002  |
| First Named Inventor   | Pascal Druzgala |
| Group Art Unit         |                 |
| Examiner Name          |                 |
| Attorney Docket Number | ARYX-102XC4Z    |

**NON PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.  | T <sup>2</sup> |
|--------------------|-----------------------|---|----------------|
|                    | R1                    | Cairns, John A., Stuart J. Connolly, Robin Roberts <i>et al.</i> (March 8, 1997) "Randomised trial of outcome after myocardial infarction in patients with frequent or repetitive ventricular premature depolarisations: CAMIAT" <i>Lancet</i> 349:675-682.   |                |
|                    | R2                    | Charlier <i>et al.</i> (1969) <i>Cardiologia</i> 54:82  |                |
|                    | R3                    | Connolly, S., J. Cairns, M. Gent <i>et al.</i> (November 15, 1997) "Effect of prophylactic amiodarone on mortality after acute myocardial infarction and in congestive heart failure: meta-analysis of individual data from 6500 patients in randomised trials" <i>Lancet</i> 350:1417-1424.                            |                |
|                    | R4                    | Juhasz, A., N. Bodor (2000) "Cardiovascular Studies on Different Classes of Soft Drugs" <i>Pharmazie</i> 55(3):228-238 (abstract only)  |                |
|                    | R5                    | Julian, D.G., A.J. Camm, G. Frangin <i>et al.</i> (March 8, 1997) "Randomised trial of effect of amiodarone on mortality in patients with left-ventricular dysfunction after recent myocardial infarction: EMIAT" <i>Lancet</i> :349:667-674.   |                |
|                    | R6                    | Kerr, Charles R. Mauricio B. Osenbaum, Pablo A. Chiale (1996) "Amiodarone" <i>In: Cardiovascular Drug Therapy</i> , Editor: Messerli, F.H.W.B. Saunders Co., 2 <sup>nd</sup> Edition, Chapter 138, pages 1247-1264.   |                |
|                    | R7                    | Kowey, Peter R., Joseph H. Levine, John M. Herre <i>et al.</i> (December 1, 1995) "Randomized, Double-Blind Comparison of Intravenous Amiodarone and Bretylium in the Treatment of Patients with Recurrent, Hemodynamically Destabilizing Ventricular Tachycardia or Fibrillation" <i>Circulation</i> 92(11):3255-3263. |                |
|                    | R8                    | Naccarelli, Gerald, Robert L. Rinkenberger, Anne H. Dougherty, Ruth A. Giebel (Nov/Dec. 1985) "Evaluations of New Drugs: Amiodarone: Pharmacology and Antiarrhythmic and Adverse Effects" <i>Pharmacotherapy</i> 5(6):298-313.  |                |
|                    | R9                    | Rosenbaum, Mauricio B., Pablo A. Chiale, M. susana Halpern <i>et al.</i> (December 1976) "Clinical Efficacy of Amiodarone as an Antiarrhythmic Agent" <i>The American Journal of Cardiology</i> 38:934-944.   |                |
|                    | R10                   | Rosenbaum, Mauricio, Pablo A. chiale, David Ryba, Marcelo V. elizari (August 1974) "Control of Tachyarrhythmias Associated with Wolff-Parkinson-White Syndrome by Amiodarone Hydrochloride" <i>The American Journal of Cardiology</i> 34:215-223.   |                |
|                    | R11                   | Singh, B.N. and E.M. Vaughan Williams (1970) "The effect of amiodarone, a new anti-anginal drug, on cardiac muscle" <i>Br. J. Pharmacol</i> 39:657-667  |                |
|                    | R12                   | Vrobel, Thomas R., Paul E. Miller, Nelson D. Mostow, Louis Rakita (May/June 1989) "A General Overview of Amiodarone Toxicity: Its Prevention, Detection, and Management" <i>Progress in Cardiovascular Diseases</i> 31(6):393-426.  |                |
|                    | R13                   |   |                |

|                    |                 |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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